REMARKS

Claims 1, 3-7, 20, 21, 35-37, 39, 41, 43, 45 and 49 are pending. Claims 36, 37, 39, 41, 43, and 45 are withdrawn from consideration. Claims 1, 3-7, 20, 21, 35, and 49 stand rejected.

No claims are amended in the current submission.

Reconsideration of the application is requested.

§ 103 Rejections

Claims 1, 3-7, 20, 21, 35, and 49 stand rejected under 35 USC § 103(a) as being unpatentable over Griesgraber (US 6,677,349) in view of Hedenstrom et al. (US 6,706,728) and Gizurarson (US 6,647,980) and further in view of Kublik et al. ("Nasal delivery systems and their effect on deposition and absortption" in Advanced Drug Delivery Reviews, 29 (1998), pp 157-177) (hereinafter, "Kublik"). Applicants respectfully traverse.

Independent claim 1 calls for:

1. An aqueous sprayable formulation for delivery of an immune response modifier to the nasal passage of a subject comprising:

an immune response modifier, wherein the immune response modifier is N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide, or a pharmaceutically acceptable salt thereof;

water; and

a hydrophilic viscosity enhancing agent;

with the proviso that the hydrophilic viscosity enhancing agent is not covalently bonded to the immune response modifier;

wherein the formulation is a solution at room temperature, has a viscosity of less than 100 cps at room temperature, and is contained in a nasal spray device.

It would not have been reasonably predictable based on the cited art that, for example, the claimed compound would be soluble in the claimed aqueous formulation, or that the compound would be released and biologically effective when formulated as claimed. While certain features of the claimed invention may be disclosed independently in Griesgraber, Hedenstrom et al.,

Gizurarson, and Kublik et al., there was no basis at the time for one of ordinary skill to have concluded in a predictable manner that N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide would dissolve sufficiently in an aqueous nasal formulation or be biologically effective when delivered.

For example, the IRM compound imiquimod (the only commercialized IRM compound at the time) is highly insoluble in water and therefore was dissolved in isostearic acid to form an oil-in-water emulsion rather than, e.g., an aqueous gel formulation (see, e.g., Chollet et al., "Development of a Topically Active Imiquimod Formulation", Pharmaceutical Development and Technology, 4(1), 35-43 (1999), of record. Without knowing the solubility and release characteristics of N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide, one would have had no reasonable basis to predict that the compound of the present claims could have been dissolved in an aqueous nasal formulation or that such formulation would release the drug for biologic effectiveness.

Accordingly, Applicants submit that the claimed invention would not have been obvious based on the asserted combination of Griesgraber, Hedenstrom et al., Gizurarson, and Kublik et al.

In view of the above, it is submitted that the application is in condition for allowance.

Examination and reconsideration of the application as amended is requested.

Respectfully submitted,

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